

Express Mail Label No. EL 867734858 US  
Date of Deposit: September 28, 2001

Bayer 10,139.4-KGB  
Le A 31 651-US LH/AA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : THOMAS KRAHN ET AL.  
SERIAL NO. : DIVISION OF U.S. SERIAL NO. 09/194,099 FILED ON  
NOVEMBER 20, 1998  
FILED : HEREWITH  
FOR : MASKING BACKGROUND FLUORESCENCE AND  
LUMINESCENCE IN OPTICAL ANALYSIS OF BIOMEDICAL  
ASSAYS  
ART UNIT : UNASSIGNED  
EXAMINER : UNASSIGNED

---

September 28, 2001

Hon. Commissioner of Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

SIR:

Prior to examination, please amend the above-identified application as follows:

IN THE SPECIFICATION:

Insert as the first paragraph of the specification the following new paragraph: -- This application is a division of U.S. Serial No. 09/194,099, filed on November 20, 1998, now pending. --

IN THE CLAIMS:

Cancel all of the claims in the application and substitute the following new claims:

- 7.           A composition of matter comprising:
- a)       a reaction vessel having a transparent support at the bottom of said reaction vessel;
  - b)       a coherent layer of fluorescently labeled biological cells applied to the transparent support;
  - c)       a solution comprising a masking dye in the reaction vessel, the masking dye absorbing at least one of:
    - i)       the excitation energy of any fluorescent dye in the solution;  
and
    - ii)      the emission light of any fluorescent dye in the solution; and

0966137-092904  
T09250-4ET9550

d) optionally a fluorescent dye in the solution. --

--8. The composition of matter according to claim 7, wherein the masking dye is water-soluble and has no cytotoxic side effects. --

--9. A composition of matter comprising:

- a) a reaction vessel having a transparent support at the bottom of said reaction vessel;
- b) a coherent layer of fluorescently labeled biological cells applied to the transparent support;
- c) a separating layer applied to the coherent layer of fluorescently labeled biological cells, the separating layer being permeable to a solution comprising a fluorescent dye, and the separating layer absorbing, reflecting or both absorbing and reflecting at least one of:
  - i) the excitation energy of the fluorescent dye in the solution;

and

ii) the emission light of the fluorescent dye in the solution; and

d) optionally a solution comprising a fluorescent dye in the reaction vessel. --

--10. The composition of matter according to claim 9, wherein the separating layer comprises a layer of polymeric latex beads. --

--11. The composition of matter according to claim 10, wherein the polymeric latex beads are dyed with a masking dye. --

--12. The composition of matter according to claim 11, wherein the masking dye dyed on the polymeric latex beads is water-soluble and has no cytotoxic side effects. --

--13. A composition of matter comprising:

a) a reaction vessel having a transparent support at the bottom of said reaction vessel;

- b) a coherent layer of fluorescently labeled biological cells applied to the transparent support;
- c) a solution comprising a masking dye in the reaction vessel, the masking dye absorbing at least one of:
  - i) the excitation energy of any fluorescent dye in the solution; and
  - ii) the emission light of any fluorescent dye in the solution; and
- d) a separating layer applied to the coherent layer of fluorescently labeled biological cells, the separating layer being permeable to a solution comprising a fluorescent dye, and the separating layer absorbing, reflecting or both absorbing and reflecting at least one of:
  - i) the excitation energy of the fluorescent dye in the solution; and

ii) the emission light of the fluorescent dye in the solution; and

f) optionally a fluorescent dye in the solution. --

--14. The composition of matter according to claim 13, wherein the masking dye is water-soluble and has no cytotoxic side effects. --

--15. The composition of matter according to claim 13, wherein the separating layer comprises a layer of polymeric latex beads. --

--16. The composition of matter according to claim 15, wherein the polymeric latex beads are dyed with a masking dye. --

--17. The composition of matter according to claim 16, wherein the masking dye dyed on the polymeric latex beads is water-soluble and has no cytotoxic side effects. --

--18. A composition of matter comprising:

a) a reaction vessel having a transparent support at the bottom of said reaction vessel;

- b) a coherent layer of luminescent biological cells applied to the transparent support;
- c) a solution above the coherent layer of luminescent biological cells; and
- d) a separating layer applied to the coherent layer of luminescent biological cells, the separating layer being permeable to the solution, and the separating layer reflecting luminescent radiation emitted by the coherent layer of luminescent biological cells. — —

—19. The composition of matter according to claim 18, wherein the separating layer comprises a layer of polymeric latex beads. — —

—20. The composition of matter according to claim 19, wherein the polymeric latex beads are dyed with a masking dye. — —

—21. The composition of matter according to claim 20, wherein the masking dye dyed on the polymeric latex beads is water-soluble and has no cytotoxic side effects. — —

--22. A composition of matter comprising:

- a) a reaction vessel having a transparent support at the bottom of said reaction vessel;
- b) a layer of receptors specific for a fluorescent or luminescent ligand applied to or deposited on the transparent support; and
- c) a solution comprising a masking dye in the reaction vessel, the masking dye masking the fluorescence or luminescence of any unbound fluorescent or luminescent ligand in the solution. --

--23. The composition of matter according to claim 22, wherein the masking dye is water-soluble and has no cytotoxic side effects. --

--24. A composition of matter comprising:

- a) a reaction vessel having a transparent support at the bottom of said reaction vessel;



- b) a layer of receptors specific for a fluorescent or luminescent ligand applied to or deposited on the transparent support; and
- c) a separating layer applied to the layer of receptors specific for a fluorescent or luminescent ligand, the separating layer being permeable to a solution comprising the fluorescent or luminescent ligand, and the separating layer absorbing, reflecting or both absorbing and reflecting at least one of:
  - i) the excitation energy of any unbound fluorescent or luminescent ligand remaining in the solution comprising the fluorescent or luminescent ligand; and
  - ii) the fluorescence or luminescence of any unbound fluorescent or luminescent ligand remaining in the solution comprising the fluorescent or luminescent ligand. --

--25. The composition of matter according to claim 24, wherein the separating layer comprises a layer of polymeric latex beads. --

--26. The composition of matter according to claim 25, wherein the polymeric latex beads are dyed with a masking dye. --

--27. The composition of matter according to claim 26, wherein the masking dye dyed on the polymeric latex beads is water-soluble and has no cytotoxic side effects. --

--28. A composition of matter comprising:

- a) a reaction vessel having a transparent support at the bottom of said reaction vessel;
- b) a layer of receptors specific for a fluorescent or luminescent ligand applied to or deposited on the transparent support;
- c) a solution comprising a masking dye in the reaction vessel, the masking dye masking the fluorescence or luminescence of any unbound fluorescent or luminescent ligand in the solution; and
- d) a separating layer applied to the layer of receptors specific for a fluorescent or luminescent ligand, the separating layer being

permeable to a solution comprising the fluorescent or luminescent ligand, and the separating layer absorbing, reflecting or both absorbing and reflecting at least one of:

- i) the excitation energy of any unbound fluorescent or luminescent ligand remaining in the solution comprising the fluorescent or luminescent ligand; and
- ii) the fluorescence or luminescence of any unbound fluorescent or luminescent ligand remaining in the solution comprising the fluorescent or luminescent ligand. --

--29. The composition of matter according to claim 28, wherein the masking dye is water-soluble and has no cytotoxic side effects. --

--30. The composition of matter according to claim 28, wherein the separating layer comprises a layer of polymeric latex beads. --

--31. The composition of matter according to claim 30, wherein the polymeric latex beads are dyed with a masking dye. --

--32. The composition of matter according to claim 31, wherein the masking dye dyed on the polymeric latex beads is water-soluble and has no cytotoxic side effects. --

--33. A kit comprising:

a) a masking dye absorbing at least one of:

i) the excitation energy of a fluorescent dye; and

ii) the emission light of a fluorescent dye; and

b) a fluorescent dye. --

--34. The kit according to claim 33, wherein the masking dye is water-soluble and has no cytotoxic side effects. --

--35. A kit comprising:

a) precursors of a separating layer, the separating layer being permeable to a solution comprising a fluorescent dye, and the

separating layer absorbing, reflecting or both absorbing and reflecting at least one of:

i) the excitation energy of the fluorescent dye; and

ii) the emission light of the fluorescent dye; and

b) a fluorescent dye. --

--36. The kit according to claim 35, wherein the precursors are polymeric latex beads. --

--37. The kit according to claim 36, wherein the polymeric latex beads are dyed with a masking dye. --

--38. The kit according to claim 37, wherein the masking dye dyed on the polymeric latex beads is water-soluble and has no cytotoxic side effects. --

--39. A kit comprising:

- a) a masking dye absorbing at least one of:
  - i) the excitation energy of a fluorescent dye; and
  - ii) the emission light of a fluorescent dye;
- b) precursors of a separating layer, the separating layer being permeable to a solution comprising a fluorescent dye, and the separating layer absorbing, reflecting or both absorbing and reflecting at least one of:
  - i) the excitation energy of the fluorescent dye; and
  - ii) the emission light of the fluorescent dye; and
- c) optionally a fluorescent dye. --

--40. The kit according to claim 39, wherein the masking dye is water-soluble and has no cytotoxic side effects. --

--41. The kit according to claim 39, wherein the separating layer comprises a layer of polymeric latex beads. --

--42. The kit according to claim 41, wherein the polymeric latex beads are dyed with a masking dye. --

--43. The kit according to claim 42, wherein the masking dye dyed on the polymeric latex beads is water-soluble and has no cytotoxic side effects. --

#### REMARKS

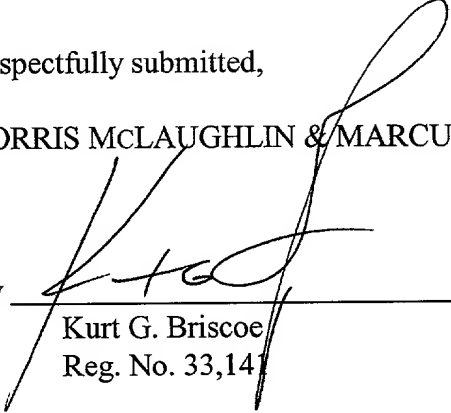
This application is a division of U.S. Serial No. 09/194,099 (hereinafter "the parent application"), which is still pending. A Notice of Allowance was received in connection with the parent application, and thereafter Applicants became aware of the last four U.S. patent documents listed on Sheet 2 of the Form PTO 1449 attached the accompanying information disclosure statement. A request has been filed to withdraw the parent application from issue to gain consideration of these references, which Applicants believe disclose and/or claim subject matter similar to that presently claimed here and in the parent application. This divisional is being filed to get coverage for compositions and kits supported by and corresponding to the method claims being prosecuted in the parent application.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By

  
Kurt G. Briscoe  
Reg. No. 33,141

220 East 42<sup>nd</sup> Street  
30<sup>th</sup> Floor  
New York, New York 10017  
Phone: (212) 808-0700  
Fax: (212) 808-0700